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Volatile Organic Compound Emission Controls for Tablet Coating at Pharmaceutical Plants

PEDCo-Environmental, Inc., Arlington, TX

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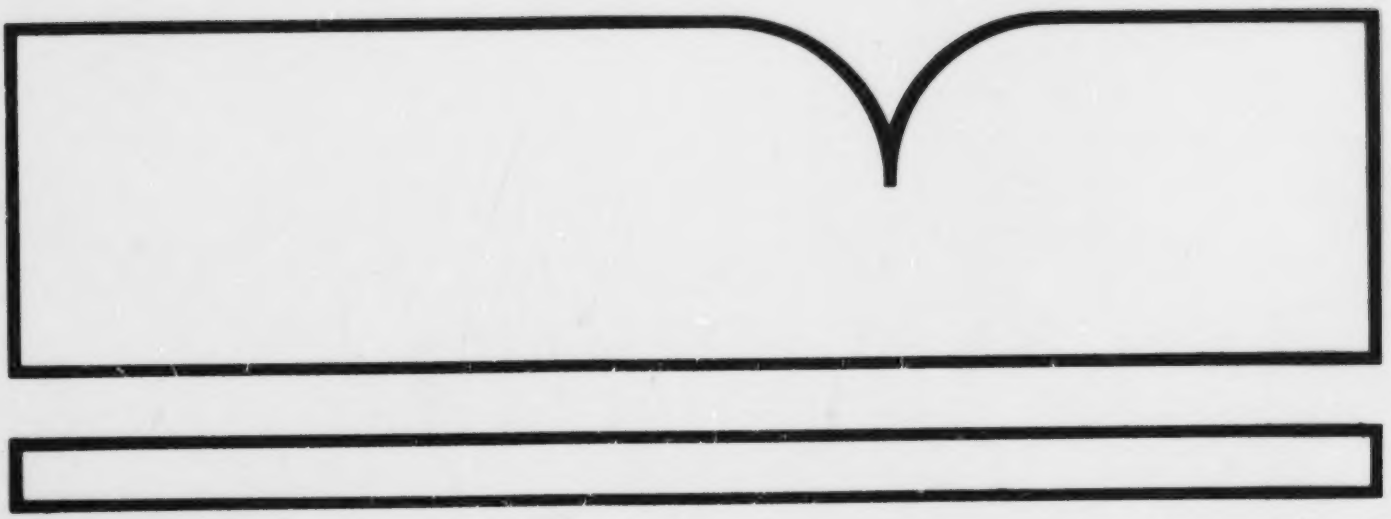

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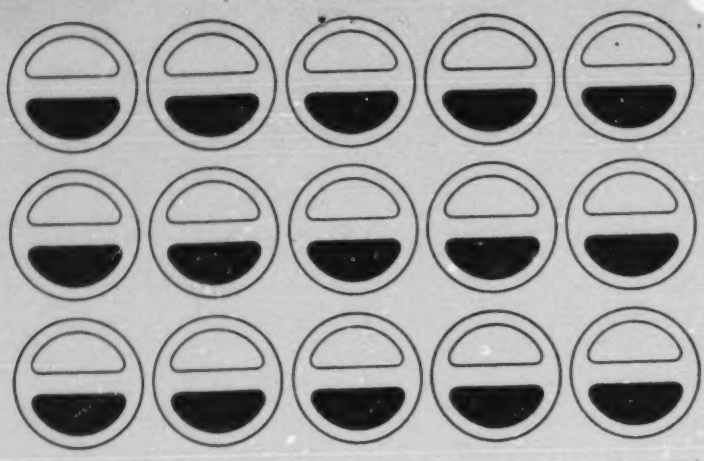

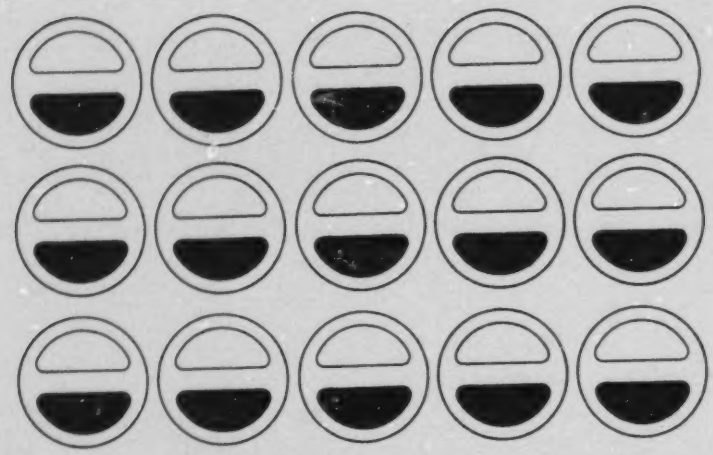

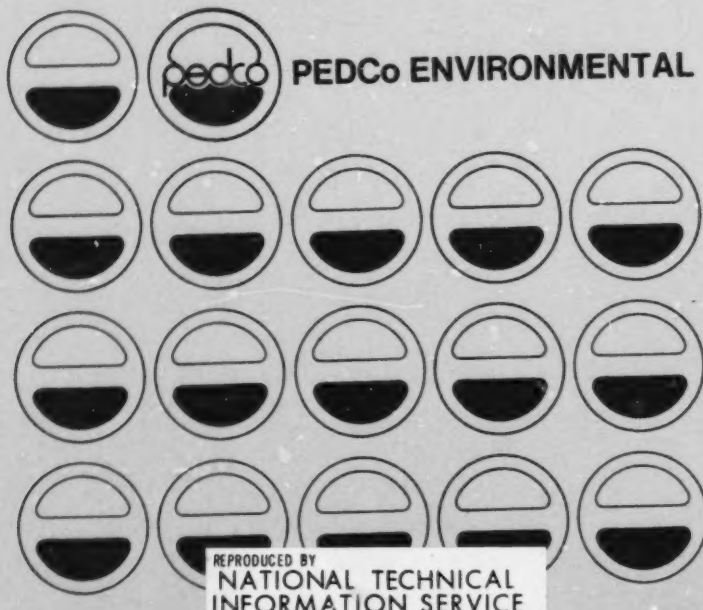

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16. ABSTRACT

Pharmaceutical plants coat tablets with either a water-based or organic-based material in a batch operation that uses rotating open-ended pans. After being coated, the tablets are dried by hot air. Most tablets are coated with sugar, methyl cellulose, or ethyl cellulose. Because sugar coatings are water-based, they are not a source of volatile organic compound (VOC) emissions. Cellulose coatings can be applied either in water or in an organic media. An organic solvent is used if faster drying is required or if the tablet is sensitive to water and/or heat. This process is often referred to as film coating. A typical organic spray is 80 to 85% methylene chloride, 10% denatured alcohol or isopropanol, and 5 to 10% solids (methyl or ethyl cellulose). Chloroform is frequently used in place of methylene chloride.

The most practical VOC emission control method is adsorption of the VOC stream onto activated carbon. The pharmaceutical industry currently uses this method to control VOC emissions from tablet coating operations. Carbon adsorbers are rugged and simple to operate, and the recovered methylene chloride or chloroform is suitable for reuse without further treatment. Ethanol and isopropanol are recovered in dilute aqueous solutions that can be processed in the plant wastewater treatment facility. Incineration and refrigeration control methods are technically feasible, but uneconomic.

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VOLATILE ORGANIC COMPOUND EMISSION CONTROLS FOR TABLET COATING AT PHARMACEUTICAL PLANTS

by

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1006 N. Bowen Road
Arlington, Texas 76012

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Project Officer

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U.S. ENVIRONMENTAL PROTECTION AGENCY
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CONTENTS

		Page
Tables		iii
Summary		iv
1.	Introduction	1
1.1	Source Description and Types of VOC Emissions	1
2.	Emission Control Techniques	5
3.	Cost Analysis	7
3.1	Model plants	7
3.2	Assumptions	7
3.3	Capital and annual costs	8
3.4	Cost-effectiveness	10
4.	Regulatory Analysis	15
4.1	Draft regulation	15
4.2	Regulation in other areas	18
4.3	Compliance and monitoring techniques	18
4.4	Potential problem areas	20
References		21
Appendix		
A	List of Pharmaceutical Manufacturing Plants in the Philadelphia AQCR	A-1
B	Calculations and Material Balances Around Carbon Adsorbers Used to Control VOC Emissions During Tablet Coating	B-1
C	Texas Air Control Board Regulation V, Control of Air Pollution From Volatile Organic Compounds, Sections 115.231, 115.232, and 115.233	C-1

TABLES

Number		Page
1	Cost of Carbon Adsorber As VOC Control Technique for Pharmaceutical Tablet Coating Operations	11
2	Costs of A 1000-cfm Adsorber As A VOC Control Technique At Various Utilization Rates	12
3	Costs of Catalytic Incinerator-Scrubber Control As VOC Control Technique for Pharmaceutical Tablet Coating Operations	14
4	Costs of Refrigerated Vapor Recovery As A VOC Control Technique for Pharmaceutical Tablet Coating Operations	15

SUMMARY

Pharmaceutical plants coat tablets with either a water-based or organic-based material in a batch operation that uses rotating open-ended pans. After being coated, the tablets are dried by hot air. Most tablets are coated with sugar, methyl cellulose, or ethyl cellulose. Because sugar coatings are water-based, they are not a source of volatile organic compound (VOC) emissions. Cellulose coatings can be applied either in water or in an organic media. An organic solvent is used if faster drying is required or if the tablet is sensitive to water and/or heat. This process is often referred to as film coating. A typical organic spray is 80 to 85 percent methylene chloride, 10 percent denatured alcohol or isopropanol, and 5 to 10 percent solids (methyl or ethyl cellulose). Chloroform is frequently used in place of methylene chloride.

The most practical VOC emission control method is adsorption of the VOC stream onto activated carbon. The pharmaceutical industry currently uses this method to control VOC emissions from tablet coating operations. Carbon adsorbers are rugged and simple to operate, and the recovered methylene chloride or chloroform is suitable for reuse without further treatment. Ethanol and isopropanol are recovered in dilute aqueous solutions that can be processed in the plant wastewater treatment facility. Incineration and refrigeration control methods are technically feasible, but uneconomic. Also, the incinerator exhaust is a potential source of poisonous and corrosive emissions.

This report includes a draft regulation for tablet coating processes that emit 33 pounds or more VOC per day. This regulation requires the plant to maintain purchasing and inventory records of solvents, production equipment schedules, and operating schedules of all control devices, and to have those records available for examination. It also includes a 2-year compliance schedule, with the understanding that some flexibility may be required for specific plants to obtain Food and Drug Administration (FDA) approval of process modifications.

SECTION 1
INTRODUCTION

Over the past several years the Office of Air Quality Planning and Standards (OAQPS) has developed a series of Control Techniques Guidelines (CTGs) covering volatile organic compounds (VOC) to assist state and local agencies in developing regulations for VOC control. Although these CTGs have covered major VOC source categories from an overall nationwide perspective, they do not cover several VOC source categories that are major contributors to ozone problems within given areas.

Air pollution control agencies in the Philadelphia Air Quality Control Region (AQCR) have requested guidance in determining whether VOC controls are available for non-CTG sources so they can develop appropriate regulations. One VOC source category under investigation is tablet coating at pharmaceutical plants. The pharmaceutical industry includes three SIC codes: 2831-Biological Products; 2833-Medicinal Chemicals and Botanical Products; and 2834-Pharmaceutical Preparations. Appendix A contains a list of the pharmaceutical plants in the Philadelphia AQCR.

1.1 SOURCE DESCRIPTION AND TYPES OF VOC EMISSIONS

In contrast with most other chemical manufacturing operations, the pharmaceutical industry generally produces small quantities of very expensive materials. For example, the price per pound of a 59-cent bottle of 100 aspirins is about $8; prescription drugs generally cost one or two orders of magnitude more. Production is normally in small-scale batch operations and 800 pounds is considered a large run. After one product has been made, the equipment often is cleaned and used to make a different product.

Tablets are coated in rotating open-ended pans that range from 36 to 60 inches in diameter. The coating is sprayed on the tablets in the pan while warm air (100°F) flows across the pan at a typical rate of 1000 cubic feet per minute. Spray coating and drying takes 2 to 3 hours per batch. Figure 1

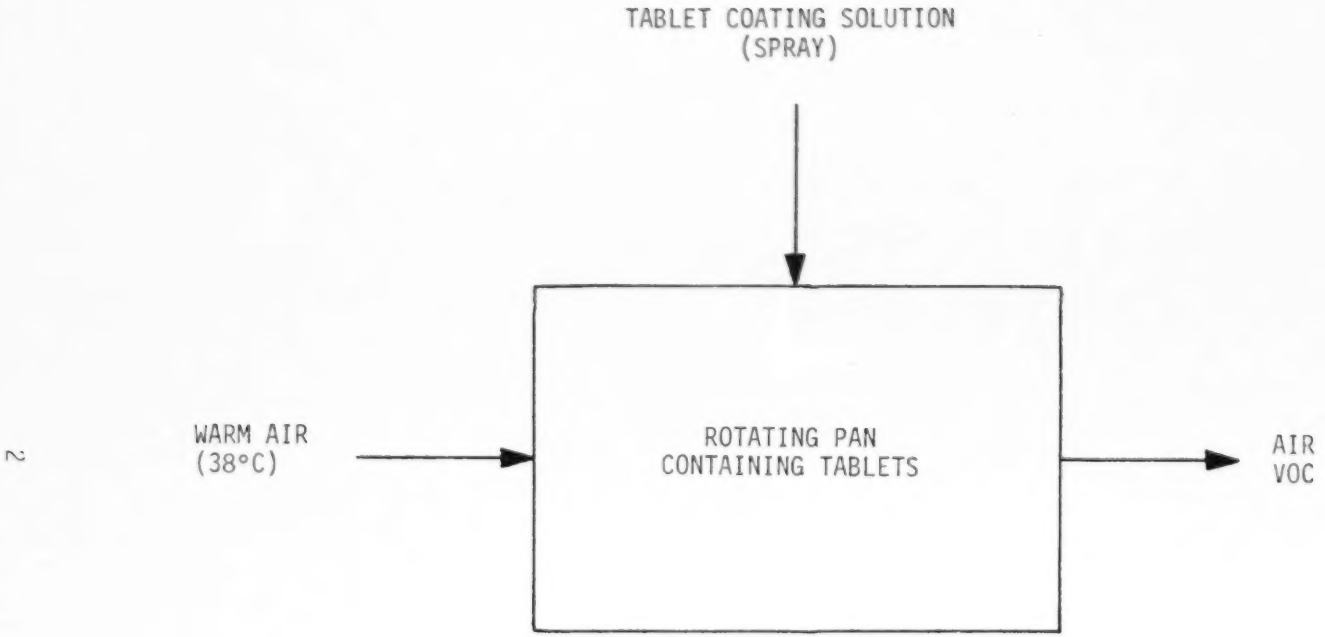

Figure 1. Tablet coating in pans.

presents a flow diagram of this tablet coating operation. A large plant might have 20 pans; a small plant might have only two. Any number of pans can be in use at any given time. The pans are usually cleaned after each batch, even if multiple batches of the same material are made.

Pharmaceutical products also may be coated by the Wurster process. As shown in Figure 2, in this process the tablets or pellets are suspended in a fluidized bed while the spray solution is applied. This method is used most often for coating pellets (smaller particles that are later encapulated), whereas coating pans are used most often for coating tablets (standard dosages). A good example of pellet coating would be the contents of over-the-counter 12-hour cold capsules. Tablet coating by the Wurster process requires a much higher air flow rate than that required for tablet coating in pans. For a 800-pound batch, the Wurster process typically requires 5000 cfm as compared to 1000 cfm for pan coating, even though both processes emit equal amounts of VOCs.

Most tablets are coated with sugar, methyl cellulose, or ethyl cellulose. Sugar-water solutions are not a source of VOC emissions. Cellulose coatings may use either a water or an organic solvent. The use of water as a solvent or solvent component reduces VOC emissions, but more time and heat are required to evaporate the water than an organic medium. This is a production consideration. Also, products that are sensitive to water and/or heat may preclude the use of aqueous coatings. The use of heat or vacuum can expedite evaporation, but this rapid evaporation can peel or roughen the coating.

A typical organic coating solution consists of 80 to 85 percent methylene chloride, 10 percent denatured ethanol or isopropanol, and 5 to 10 percent solids (methyl or ethyl cellulose), (D. Burkit, PEDCo, Inc., personal communication, September 28, 1983 and J. Jefferson, PEDCo, Inc., personal communication, December 14, 1983). Chloroform can be used in place of methylene chloride. One gallon of coating solution will generally process 25 pounds of tablets.

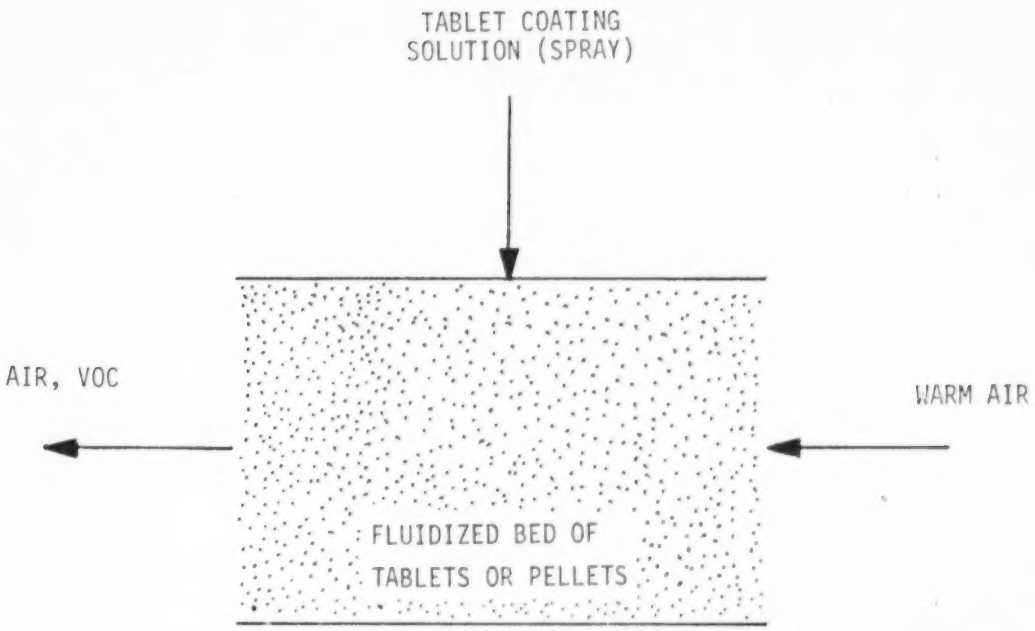

Figure 2. Tablet coating by the Wurster Process.

SECTION 2
EMISSION CONTROL TECHNIQUES

The most practical method by which to control VOC emissions from the tablet coating process entails the use of activated carbon adsorption. The pharmaceutical industry already uses this method, especially to recover methylene chloride solvent (N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982). Although methylene chloride is not regulated as a VOC, it meets the definition of a volatile organic compound and is a good example.

In this control method, the VOC-contaminated air from the dryer is passed through a bed of activated carbon. When the carbon bed becomes loaded with organic compounds, it is stripped with low-pressure steam. Because methylene chloride is insoluble in water, it is easy to separate from the steam condensate for reuse. Any ethanol that is captured is miscible with the steam condensate and is impractical to salvage. The condensate, which contains 1 to 2 percent alcohol, is usually discarded to the sewer. In a large pharmaceutical plant, this waste water stream is processed in the plant wastewater treatment system. Discharges from such streams are subject to all applicable Federal, State, and local wastewater regulations.

Carbon adsorbers are especially suitable for recovering water-insoluble chlorinated hydrocarbons from dilute air streams. Methylene chloride is recoverable at a purity that makes it suitable for reuse. Standard designs of these adsorbers are commercially available, and they are rugged and simple to operate. They are constructed of stainless steel to withstand the methylene chloride, and a particulate filter is placed upstream to remove suspended solids. An adsorber should operate at an efficiency of 90 percent.

Incineration is a technically feasible method of controlling VOC emissions; however, when methylene chloride is burned, it produces chlorine, hydrogen chloride, and phosgene, which are all corrosive and toxic materials. An incinerator for organic chlorides also requires special construction materials and a caustic scrubber to treat the incinerator exhaust. Inasmuch as

the overall control efficiency of such an incinerator-scrubber system is only 80 percent, incineration does not appear to be a practical VOC control method. This opinion is shared by California's South Coast Air Quality Management District (Los Angeles area), (G. Rhett, Senior Air Quality Engineer, South Coast Air Quality Management District, personal communication, November 29, 1982).

Refrigeration also is a technically feasible method of controlling VOC emissions from tablet coating operations; however, the high cost of cooling the dilute air stream to achieve a 90 percent system efficiency makes the method economically prohibitive. The vapor pressure of methylene chloride is 1 mm Hg at -94°F. With 100°F inlet air at 10 percent relative humidity, cooling 1000 cfm of air from one large pan would require 58 tons of refrigeration.[1]

A potential VOC control strategy is either to substitute water-based coatings for organic-based coatings or to leave the tablets uncoated. The high costs of organic solvents have already led most manufacturers to use these two options. For tablets that are susceptible to heat or water, however, solvent-based coatings seem to be the only feasible coating method. Consequently, substantial further reductions in emissions as a result of additional conversion to water-based coatings do not seem likely.

Reformulation of coatings to contain smaller percentages of VOC is not considered a feasible strategy because all new coatings have to be approved by the FDA, which would take a long time.

3. COST ANALYSIS

Although cost estimates have been developed for VOC control of methylene chloride by carbon adsorption, incineration, and refrigeration, these same VOC controls and costs apply to chloroform. Only the economics of coating pan operations are considered in these estimates. Because the Wurster Process has a much greater air volume, the economics for VOC control would be much less favorable with this process. All of these control methods are technically feasible, but incineration and refrigeration are prohibitively expensive. Therefore, this report focuses on VOC control by carbon adsorption. For the Wurster process only carbon adsorption was considered.

3.1 MODEL PLANTS

For the Wurster process, costs are based on an adsorber capacity of 5000 cfm drying an 800-pound batch. Costs in pan coating operations have been developed for plants having adsorber capacities of 1,000, 2,000, 5,000, and 10,000 cfm of VOC-laden air. Each 1,000 cfm of adsorber capacity controls emissions from a single large tablet coating pan or an equivalent amount of emissions from a number of smaller pans. An absorber with a capacity of 1,000 cfm will usually serve a small plant; one with a capacity of 2,000 or 5,000 cfm, a medium-sized plant; and one with a capacity of 10,000 cfm, a large plant. A small plant that uses organic-based coatings exclusively, however, might be a larger VOC source than a much larger plant that uses numerous water-based coatings.

3.2 ASSUMPTIONS

A base case adsorber capacity of 1000 cfm is assumed, to correspond with the air flow required to dry an 800-pound batch of tablets. One gallon of coating material is used for each 25 pounds of tablets; thus, each batch requires 32 gallons of coating material. The coating material is 80 volume

percent methylene chloride, 10 volume percent ethanol or isopropanol, and 10 volume percent solids. An air temperature of 100°F, and a required drying time of 2 hours are assumed (J. Jefferson, PEDCo, Inc., personal communication, November 24, 1982). Vic Manufacturing Company estimates that 90 percent of the solvent evaporates in the first 30 minutes and 99 percent in the first 60 minutes (N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982). After 1 hour, the carbon adsorber is regenerated with low-pressure steam.

Proper sizing of the carbon adsorber requires an estimation of the amounts and concentrations of the solvents in the carrier air stream during the adsorption cycle. Because the volume of ethanol or isopropanol is small, the alcohol concentration is always less than 25 percent of the lower explosive limit.[2] The combined methylene chloride and alcohol load is about 300 pounds for each adsorber cycle, which requires the use of about 6000 pounds of activated carbon in the adsorber. Low-pressure steam is used to regenerate the bed, and about 5 pounds of steam is required to remove 1 pound of organic material (J. Jefferson, PEDCo, Inc., personal communication, November 24, 1982). With this information, the ethanol or isopropanol concentrations in the wastewater stream can then be determined. Step-by-step calculations are presented in Appendix B.

3.3 CAPITAL AND ANNUAL COSTS

Vic Manufacturing Company has estimated equipment costs for 1,800-, 5,000-, and 10,000-cfm units (N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982). These estimates suggest that a 0.6 power rule is appropriate for estimating costs for units of various sizes, and the 0.6 power rule was used to develop the costs for the model plants. The Vic estimates provide for materials of construction that will withstand prolonged exposure to methylene chloride. Vic estimated installation costs to be 70 percent of equipment costs (T. Cannon, Vic Manufacturing Company, personal communication, December 20, 1982).

A comparison of the Vic cost estimates (N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982) for a 1000-cfm absorber with estimated costs from the Gard report showed that the Vic estimate was

approximately 80 percent of the latter, which is a favorable comparison. The Vic estimates were used because they are specifically for handling chlorinated hydrocarbons.

The capital recovery factor for carbon adsorber systems is based on a 20-year life and a 10 percent interest rate. This factor (11.75 percent), nonvariable operating and maintenance costs (estimated at 4.75 percent), and property taxes and insurance (estimated at 4.0 percent) add up to 20.5 percent of the total capital cost. Low-pressure steam is estimated to cost $3.50/1000 pounds (L. Nisbet, PEDCo, Inc., personal communication, December 1, 1982). Vic estimated that 3 to 4 pounds of steam would be needed to strip 1 pound of methylene chloride (N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982). Five pounds of steam per pound of organic compound was used in this report because alcohol is also present.

The plant is assumed to operate 8 hours per day, 5 days per week, 52 weeks per year (2080 hours per year). Solvent credits are based on 90 percent recovery (fraction of VOC entering adsorber x adsorber efficiency) and a quoted solvent price of 26.5 cents per pound of methylene chloride.[3]

For calculation of the control costs, the adsorber was estimated to operate 50 percent of the time (1040 hours per year). The tablet coating operation was estimated to take 2 hours, with 99 percent of the solvent being evaporated in the first 60 minutes (N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982). The adsorber operates only during the first hour of the tablet coating operation; it is regenerated during the second hour. There is little advantage to running the very dilute solvent stream through the adsorber during the second hour; the concentration is so low that it will actually strip methylene chloride from the adsorber.

Capital costs of catalytic incinerators and scrubbers were obtained from a published report[1] and updated to September 1982 dollars by use of cost indices published in Chemical Engineering. The economics for catalytic incinerators were presented because they represent the lowest-cost incineration option. The capital recovery factor is based on a 10 percent interest rate and a 10-year equipment life, which is appropriate for a system that handles hydrogen chloride, chlorine, and phosgene (combustion reaction products) at high temperatures.

Property taxes and insurance were assumed to be 4 percent of total capital cost, the same as for the carbon adsorber systems. Forty-two percent of the total capital cost was used for annual operating, maintenance, and material costs. This value is based on 46 percent of capital costs for a catalytic incinerator in an EPA report[4] and 37 percent for a larger incinerator-scrubber system used to control emissions at a chemical plant.[5] The 90 percent availability factor was based on 9 years of operating experience at this plant.

Capital and operating costs for VOC control by refrigeration were obtained from a published report[1] and updated to September 1982 dollars by using cost indices published in Chemical Engineering. The capital recovery charge is based on a 10 percent interest rate and a 12-year equipment life.[1] Operating, maintenance, and material costs are 2.4 percent of capital costs.[1] Property taxes and insurance are 4 percent of capital costs. To achieve a 90 percent system efficiency requires that the temperature of the air-methylene chloride stream be cooled to at least -90°F. This would require 58 tons of refrigeration for the 1000-cfm stream from one large drying pan.

3.5 COST-EFFECTIVENESS

Capital and annual cost data for the carbon adsorption control technique are summarized in Tables 1 and 2. Methylene chloride recovery by carbon adsorption for tablet coating in pans is potentially profitable, and this profitability is enhanced as the equipment size increases and as the percent utilization increases. Table 1 shows that for 50 percent equipment utilization, a 1000 cfm adsorber has an annual credit of $1900 and a 10,000 cfm adsorber has an annual credit of $171,000. Table 2 shows that the net credit for the 1000 cfm adsorber increases as the percent utilization increases. For obvious reasons, carbon adsorption is extensively used in the pharmaceutical industry to recover methylene chloride from tablet coating and drying operations (J. Jefferson, PEDCo, Inc., personal communication, December 14, 1982, N. R. Shaw, Vic Manufacturing Company, personal communication, December 6, 1982, and L. Nisbet, PEDCo, Inc., personal communication, December 1, 1982).

The economics for VOC control in the Wurster process are less favorable due to the higher air consumption. A 5000 cfm adsorber would control emissions from one 800-pound batch in the Wurster process as compared with five

TABLE 1. COSTS OF CARBON ADSORBER AS VOC CONTROL TECHNIQUE FOR PHARMACEUTICAL TABLET COATING OPERATIONS
(September 1982 dollars)

	Carbon adsorption unit capacity, cfm				
	Coating in pans				Wurster process
	1,000	2,000	5,000	10,000	5,000
Equipment cost	88,000	133,000	230,000	365,000	230,000
Installation costs (70% of equipment cost)	62,000	93,000	161,000	256,000	161,000
Total capital cost	150,000	226,000	391,000	621,000	391,000
Capital recovery factor	17,600	26,600	45,900	73,000	45,900
Operating and maintenance costs	7,100	10,700	18,600	29,500	18,600
Property taxes and insurance	6,000	9,000	15,600	24,800	15,600
Steam cost	2,500	5,000	12,600	25,200	2,500
Total annual cost	33,200	51,300	92,700	152,500	82,600
Solvent credit	35,100	70,300	175,700	351,500	35,100
Net cost (credit)	(1,900)	(19,000)	(83,100)	(199,100)	(47,500)
Tons of VOC controlled (ethanol case)[a]	72.0	144.1	360.2	720.5	72.0
Cost (credit) per ton of VOC controlled	(26)	(132)	(231)	(276)	(660)

[a]Flow rate calculations are based on the molecular weight and density of ethanol.

TABLE 2. COSTS OF A 1000-CFM ADSORBER AS A VOC CONTROL TECHNIQUE AT VARIOUS UTILIZATION RATES
(September 1982 dollars)

	Annual hours of operation (percent utilization)				
	416 (20%)	832 (40%)	1248 (60%)	1664 (80%)	2080 (100%)
Total capital cost	150,000	150,000	150,000	150,000	150,000
Capital recovery cost	17,600	17,600	17,600	17,600	17,600
Operating and maintenance costs	7,100	7,100	7,100	7,100	7,100
Property taxes and insurance	6,000	6,000	6,000	6,000	6,000
Steam cost	1,000	2,000	3,000	4,000	5,000
Total annual cost	31,700	32,700	33,700	34,700	35,700
Solvent credit	14,100	28,100	42,200	56,200	70,300
Net cost (credit)	17,600	46,000	(8,500)	(21,500)	(34,600)
Tons of VOC controlled (ethanol case)[a]	28.8	57.6	86.5	115.3	144.1
Cost (credit) per ton of VOC controlled	610	80	(100)	(190)	(240)

[a]Flow rate of calculations are based upon the molecular weight and density of ethanol.

800-pound batches in coating pans. As seen in Table 1, the costs for VOC control in the Wurster process are considerably higher than those for emission control in coating pans.

Capital and annual costs for a catalytic incinerator-scrubber system are summarized in Table 3. (A scrubber is necessary because combustion of methylene chloride produces hydrogen chloride.) With the catalytic incinerator-scrubber, VOC control costs range from $170 to $940 per ton of VOC controlled compared with a credit of $26 to $276 per ton of VOC controlled with the carbon adsorber. Table 4 presents the costs for a refrigerated vapor recovery system. System costs for refrigeration range from $1740 to $2000 per ton of VOC controlled. Both of these systems are more expensive than the carbon adsorber. In addition, the overall control efficiency for the incinerator-scrubber is only 80 percent (it is available only 90 percent of the time at a 90 percent system efficiency). Shutdowns for repairs and maintenance would require about 10 percent of available operating time.

TABLE 3. COSTS OF CATALYTIC INCINERATOR-SCRUBBER AS VOC CONTROL TECHNIQUE FOR PHARMACEUTICAL TABLET COATING OPERATIONS (September 1982 dollars)

	Catalytic incinerator-scrubber capacity, cfm			
	1,000	2,000	5,000	10,000
Incinerator	36,900	39,800	49,700	66,700
Scrubber	12,300	13,600	16,000	20,100
Installation costs (100% of equipment cost)	49,200	53,400	65,700	86,800
Total capital cost	98,400	106,800	131,400	173,600
Capital recovery cost	16,000	17,400	21,400	28,400
Operating, maintenance, and material costs	41,300	44,900	55,200	72,900
Property taxes and insurance	3,900	4,300	5,300	6,900
Total annual cost	61,200	66,600	81,900	108,100
Tons of VOC controlled (ethanol case)[a]	64.8	130	324	649
Cost per ton of VOC controlled	940	510	250	170

[a]Flow rate calculations are based on the molecular weight and density of ethanol.

TABLE 4. COSTS OF REFRIGERATED VAPOR RECOVERY AS A VOC CONTROL TECHNIQUE FOR PHARMACEUTICAL TABLET COATING OPERATIONS
(September 1982 dollars)

	Refrigerated vapor recovery system capacity, cfm			
	1,000	2,000	5,000	10,000
Capital cost	431,000	814,000	1,964,000	3,880,000
Installation cost (100% of capital cost)	431,000	814,000	1,964,000	3,880,000
Total capital cost	862,000	1,628,000	3,928,000	7,760,000
Capital recovery cost	127,000	239,000	576,000	1,139,000
Operating, maintenance, and material costs	21,000	39,000	94,000	186,000
Property taxes and insurance	34,000	65,000	157,000	310,000
Total annual cost	182,000	343,000	827,000	1,635,000
Credit for recovered solvent	(38,000)	(76,000)	(191,000)	(382,000)
Net cost	144,000	267,000	634,000	1,253,000
Tons of VOC controlled (ethanol case)[a]	72.0	144.0	360.2	720.5
Cost per ton of VOC controlled	2,000	1,850	1,760	1,740

[a]Flow rate calculations are based on the molecular weight and density of ethanol.

4. REGULATORY ANALYSIS

This section includes a draft regulation, a discussion of tablet coating regulations in other areas, applicable compliance and monitoring techniques, and a discussion of potential problem areas.

4.1 DRAFT REGULATION

A. Definitions--

1. For the purpose of this Regulation, the general definitions apply.

2. For the purpose of this Regulation, the following definitions also apply.

   a. "Control system" means any number of control devices that are designed and operated to reduce the quantity of VOC emitted to the atmosphere.

   b. "Pharmaceutical manufacturing" means manufacturing of pharmaceutical products by any method.

   c. "Tablet coating" means applying a coating that has no medicinal value to a pharmaceutical product.

   d. "Carbon adsorber" means a device that adsorbs VOC on activated carbon in such a manner that VOC emissions to the atmosphere are reduced to not less than 90 percent of the uncontrolled VOC emission level.

B. Applicability--

This Regulation applies to all tablet coating facilities at pharmaceutical plants that have the potential to emit at least 33 pounds of VOC per day. All tablet coating takes place at the pharmaceutical plant where the tablets are manufactured. The purpose of the coating is to protect the product; therefore, it is applied as early as possible in the manufacturing process.

C. Provisions for Specific Processes--

1. The owner or operator of a pharmaceutical tablet coating facility subject to this regulation shall control VOC emissions from all

process equipment that has a VOC potential to emit at least 33 pounds of VOC per day.

2. Carbon adsorbers or equivalent controls shall be used.

3. If equivalent controls are used, the VOC emissions must be reduced by as much or more than they would be if a carbon adsorber were used.

4. The owner or operator of a pharmaceutical tablet coating facility subject to this regulation shall reduce the VOC emissions from all process equipment:

   a. By at least 90 percent if VOC emissions are at least 330 pounds per day; or

   b. To 33 pounds or less per day if VOC emissions are less than 330 pounds/day.

D. Compliance Schedules--

1. The owner or operator of a pharmaceutical tablet coating facility subject to this regulation must meet the applicable increments of progress shown in the following schedule:

   a. Submit final plans for all emission control systems and process equipment within 5 months after this regulation is in effect;

   b. Award contracts or purchase orders for all emission control systems and process equipment within 8 months after this regulation is in effect;

   c. Initiate onsite construction or installation of all emission control and process equipment within 12 months after this regulation is in effect;

   d. Complete onsite construction or installation of the emission control and process equipment within 18 months after this regulation is in effect; and

   e. Achieve final compliance, determined in accordance with E, within 24 months after this regulation is in effect.

2. The owner or operator of a pharmaceutical tablet coating facility subject to this regulation may submit to the Director, and the Director may approve, a proposed alternative compliance schedule provided:

   a. The proposed alternative compliance schedule is submitted within 3 months after this regulation is in effect;

   b. The owner or operator submits information showing the need for an alternative schedule;

c. The alternative compliance schedule contains increments of progress;

d. Sufficient documentation and certification from appropriate suppliers, contractors, manufacturers, or fabricators is submitted by the owner or operator of the pharmaceutical tablet coating facility to justify the dates proposed for the increments of progress; and

e. Final compliance is achieved as expeditiously as possible and before the photochemical oxidant attainment date.

3. The owner or operator of a pharmaceutical tablet coating facility subject to a compliance schedule of this section shall certify to the Director within 5 days after the deadline for each increment of progress, whether the required increment of progress has been met.

E. Determining Compliance

1. The owner or operator of a VOC source subject to this regulation shall demonstrate compliance by:

a. Certifying that the appropriate control equipment is in place and in use;

b. Providing the Director with certified analyses of all tablet coatings in place and in use. The analyses shall include determinations of VOC content and solids content and any other determinations requested by the Director. Analyses may be provided by the owner-operator of the source, the manufacturer of the coating solution, or an independent laboratory acceptable to the Director;

c. Maintaining VOC purchasing, inventory, and consumption records such that the Director can determine compliance;

d. Maintaining the appropriate control equipment in a manner consistent with the manufacturer's recommendations; and

e. Maintaining operating and maintenance records on the appropriate control equipment in such a manner that the Director can determine compliance.

2. The Director may require that the owner or operator of a VOC source subject to this regulation demonstrate compliance by conducting emission tests in a manner consistent with U.S. EPA standards. All tests shall be made by or under the direction of a person qualified by training and/or experience in the field of air pollution testing. The Director shall receive at least 30 days advance notice of such testing so that the Director and/or his authorized representative(s) may witness the test.

The EPA guidelines for synthesized pharmaceutical industry VOC sources set a lower limit of 33 pounds per day for air dryers and production equipment exhaust systems. The guidelines also allow an extension of the compliance schedule, if necessary, to obtain Food and Drug Administration (FDA) permits.[6] A similar guideline should apply to tablet coating operations in pharmaceutical plants because these are air drying operations.

4.2 REGULATION IN OTHER AREAS

No applicable BACT/LAER determinations, New Source Performance Standards, or other regulations were found that apply to tablet coating in the pharmaceutical industry. California's South Coast Air Quality Management District (SCAQMD) and the Texas Air Control Board have regulations similar to those proposed in EPA's CTG document. The applicability limits for California, however, is 1 ton per year. A SCAQMD representative said that the regulation covers tablet coating. A copy of the Texas regulations is included as Appendix C. The SCAQMD and Texas regulations both follow EPA guidelines and are the same with the exception of a lower cutoff limit in California. The Texas regulations apply to tablet coating processes using air dryer and exhaust systems.

4.3 COMPLIANCE AND MONITORING TECHNIQUES

Emissions can be estimated accurately from solvent inventories and purchasing records, and these records can be verified by spot inspections. The plant may also demonstate compliance by submitting monthly material balances for tablet coating operations.

Because solvent recovery by carbon adsorption is potentially profitable, many pharmaceutical companies already have carbon adsorbers in place. The principal and most frequent monitoring activities are:

1. Determining that sufficient adsorber capacity exists to control VOC emissions at all times; and

2. Determining that all significant VOC emissions are routed through control devices.

For maximum usage, an adsorber may be connected to several coating pans and/or dryers. Because of the batch operations, it is possible for more

equipment to be in operation than the adsorber can service at certain times, and that some VOC emissions might bypass the adsorber during these periods. The responsible agency should require assurance that this will not happen. It may be necessary to write a conditional operating permit that allows only those operating combinations that do not generate emissions that exceed limits.

4.4 POTENTIAL PROBLEM AREAS

If purchasing and inventory records indicate that VOC emissions are excessive, the agency may find it necessary to examine production and operating schedules to determine whether the control equipment is adequate to comply with regulations. This will necessitate obtaining the following information:

1. Operating schedules for all equipment connected to the adsorber;
2. VOC quantities potentially routed to the adsorber; and
3. Operating capacity and schedule of the adsorber.

For example, if the adsorber is regenerated during the first hour that a tablet coating pan is operating, VOC would bypass the adsorber. If the adsorbers are used at or near capacity, small fluctuations in the schedule or adsorber malfunctions could result in VOC emissions. Some reserve adsorber capacity may be appropriate. The control agency should frequently examine a company's solvent purchasing and inventory records and production schedules and have a good understanding of the capabilities of the company's control equipment.

REFERENCES

1. Neveril, R. B. Capital and Operating Costs of Selected Air Pollution Control Systems. Gard, Inc. EPA 450/5-80-002, December 1978. pp. 5-65 to 5-73.

2. McDermott, H. J. Handbook of Ventilation for Contaminant Control. Ann Arbor Science Publishers, Inc., Ann Arbor, Michigan. 1976. p. 49.

3. Price of NF Grade Methylene Chloride. Chemical Marketing Reporter, November 22, 1982.

4. U.S. Environmental Protection Agency. Control Technique Guidelines for the Control of Volatile Organic Emissions From Wood Furniture Coating. (Draft) Office of Air and Waste Management, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina. April 1979.

5. Hall, F. D. Incineration System Summary Report. Inspection and Evaluation of the Incinerator Scrubber System Used for Incinerating Organic Chlorides at PPG Industries, Lake Charles, Louisiana Plant. April 28, 1982.

6. Capone, S. V., and M. Petroccia. Guidance to State and Local Agencies in Preparing Regulations to Control Volatile Organic Compounds from Ten Stationary Source Categories. EPA-450/2-79-004, September 1979.

APPENDIX A

LIST OF PHARMACEUTICAL MANUFACTURING PLANTS
IN THE PHILADELPHIA AQCR

DELAWARE

ICI Americols, Inc.	Newark
Stuart Pharmaceuticals Division	Newark

NEW JERSEY

Elkins-Sinn, Inc.	Cherry Hill
Ganes Chemicals, Inc.	Pennsville
Heather Drug Co., Inc.	Cherry Hill

PENNSYLVANIA

American Home Products Corp.	Radner
American Home Products Corp.	Paoli
Carroll Products, Inc.	Philadelphia
Certified Laboratories, Inc.	Warrington
Gordon Laboratories	Upper Darby
High Chemical Co.	Philadelphia
Lannett Company, Inc.	Philadelphia
McNeil Laboratories, Inc.	Fort Washington
Merck, Sharpe and Dohme, Inc.	West Point
Moyco Industries, Inc.	Philadelphia
William H. Rover, Inc.	Fort Washington
Schuylkill Chemical Co.	Philadelphia
Smith, Kline and French Laboratories	Philadelphia
Smith, Kline and French Laboratories	Swedeland
Vicks Health Care Division	Hatboro
Wyeth Laboratories, Inc.	West Chester
Wyeth Laboratories, Inc.-Green Valley	Malvern

APPENDIX B

CALCULATIONS AND MATERIAL BALANCES AROUND CARBON ADSORBERS USED TO CONTROL VOC EMISSIONS DURING TABLET COATING

DESIGN CONDITIONS

1. The batch is 800 pounds; 1 gallon of coating material is used per 25 pounds of tablets (32 gallons per batch).[1]

2. The coating material composition (in volume percent) is methylene chloride, 80; ethanol or isopropanol, 10; and solids, 10.[1]

3. The air flow rate and temperature are 1000 cfm at 100°F (38°C).[1]

4. The drying period is 2 hours. Ninety percent of the solvent is evaporated in 30 minutes and 99 percent in 60 minutes.[3] The carbon adsorber is regenerated after 1 hour.

5. The lower explosion limit for ethanol is 4.3 percent; for isopropanol, it is 2.0 percent.[8]

6. Liquid densities are ethanol, 0.9182 g/ml; isopropanol, 0.7812 g/ml; and methylene chloride, 1.3266 g/ml.

VOC VOLUMES

1. Ethanol, 32 gal x 10% = 3.2 gallons

   3.2 gal x 3.785 liters/gal x 1000 ml/liter x 0.9182 g/ml ÷ 46.06 g/mole = 241.4 moles

   Vapor volume

   241.4 mole x 22.4 liters/mole x (311K/273K) x 0.03531 ft^3/liter = 218 ft^3

2. Isopropanol, 32 gal x 10% = 3.2 gal

   3.2 gal x 3.785 liters/gal x 1000 ml/liter x 0.7812 g/ml ÷ 60.09 g/mole = 157.5 moles

Vapor volume

157.5 moles x 22.4 liters/mole x (311K/273K) x 0.03531 ft^3/liter

= 142 ft^3

3. Methylene chloride, 32 gal x 80% = 25.6 gal

25.6 gal x 3.785 liters/gal x 1000 ml/liters x 1.3266 g/ml ÷ 84.93 g/mole = 1514 moles

Vapor volume

1514 moles x 22.4 liters/mole x (311K/273K) x 0.03531 ft^3/liter

= 1364 ft^3

FLOW RATES THROUGH THE CARBON BED

Air flow rate = 1000 cubic feet per minute.

1. First 30 minutes - 90 percent of VOC evaporated.

a. Ethanol + methylene chloride

Total flow = (1000 ft^3/min x 30 min) + 90% x (218 ft^3 + 1364 ft^3)

= 31,423 ft^3/30 min

= 1047 ft^3/min

Ethanol concentration:

90% x 218 ft^3/31,423 ft^3 = 0.62%

Lower explosive limit (LEL) = 4.3%

% of LEL = (0.62/4.3) x 100% = 14%

Methylene chloride concentration

90% x 1364 ft^3/31,423 ft^3 = 3.91%

b. Isopropanol + methylene chloride:

Total flow = (1000 ft^3/min x 30 min) + 90% x (142 ft^3 + 1364 ft^3)

= 31,355 ft^3/30 min

= 1,045 ft^3/min

Isopropanol concentration:

90% x 142 ft^3/31,355 ft^3 = 0.4%

LEL = 2%

% of LEL + (0.41/2) x 100% = 20%

Methylene chloride concentration:

90% x 1364 ft^3/31,355 ft^3 = 3.9%

2. Second 30 minutes - 9 percent of VOC evaporates

a. Ethanol + methylene chloride:

Total flow = (1000 ft^3/min x 30 min) + 9% x (218 ft^3 + 1364 ft^3)

= 30,142 ft^3/30 min

= 1005 ft^3/min

Ethanol concentration:

9% x 218 ft^3/30,142 ft^3 = 0.07%

Methylene chloride concentration percent:

9% x 1364 ft^3/30,142 ft^3 = 0.41%

b. Isopropanol + methylene chloride:

Total flow = (1000 ft^3/min x 30 min) + 9% x (142 ft^3 + 1364 ft^3)

= 30,136 ft^3/30 min

= 1005 ft^3/min

Isopropanol concentration:

9% x 142 ft^3/30,136 ft^3 = 0.04%

Methylene chloride concentration:

9% x 1364 ft^3/30,136 ft^3 = 0.41%

UNCONTROLLED VOC EMISSIONS PER CYCLE

1. Ethanol = 3.2 gal x (0.9182 x 8.342) lb/gal = 24.5 lb

2. Isopropanol = 3.2 gal x (0.7812 x 8.345) lb/gal = 20.9 lb

3. Methylene chloride = 25.6 gal x (1.3266 x 8.345) lb/gal = 283.4 lb

Total VOC (Ethanol + methylene chloride) = 283.4 lb + 24.5 lb = 308 lb

Assuming a capacity of 1 pound of organic vapor per 10 pounds of carbon and using a safety factor of 2.

Carbon requirement is 307.9 lb organic vapor x 10 lb carbon/lb organic vapor x 2 = 6200 lb carbon per bed

ALCOHOL CONCENTRATIONS IN WASTEWATER STREAMS

About 5 pounds of steam is required to remove 1 pound of organic vapor

Water = 308 lb organic vapor x 5 lb steam/lb organic vapor

= 1540 lb steam

Ethanol concentration = 100% x 24.5 lb/1540 lb = 1.6% in water

Isopropanol concentration = 100% x 20.9 lb/1540 lb = 1.4%

APPENDIX C

TEXAS AIR CONTROL BOARD
REGULATION V
CONTROL OF AIR POLLUTION FROM
VOLATILE ORGANIC COMPOUNDS

TEXAS AIR CONTROL BOARD

REGULATION V

(31 TAC CHAPTER 115)

CONTROL OF AIR POLLUTION

FROM VOLATILE ORGANIC COMPOUNDS

REVISED MARCH 20, 1981

(1) Facilities where an adsorber cannot be accommodated because of inadequate space.

(2) Facilities with insufficient steam capacity to desorb adsorbers.

(c) Any perchloroethylene dry cleaning facility located in Bexar, Brazoria, Dallas, El Paso, Galveston, Gregg, Jefferson, Nueces, Orange, Tarrant, or Victoria County which when uncontrolled would emit a combined weight of volatile organic compounds of less than 550 pounds (250 kg) in any consecutive 24-hour period is exempt from the provisions of §115.221 of this title (relating to Control Requirements).

§115.223. Compliance Schedule and Counties.

The provisions of §115.221 of this title (relating to Control Requirements) shall apply only within Bexar, Brazoria, Dallas, El Paso, Galveston, Gregg, Harris, Jefferson, Nueces, Orange, Tarrant, and Victoria Counties. All affected persons shall submit to the Texas Air Control Board a control plan for compliance with these provisions no later than December 31, 1980, and shall be in compliance as soon as practicable but no later than December 31, 1982.

PHARMACEUTICAL MANUFACTURING FACILITIES IN BEXAR, BRAZORIA, DALLAS, EL PASO, GALVESTON, GREGG, HARRIS, JEFFERSON, NUECES, ORANGE, TARRANT, AND VICTORIA COUNTIES

§115.231. Control Requirements.

The owner or operator of a synthesized pharmaceutical manufacturing facility shall provide the following specified controls for the following specific sources in his facility:

(1) Reactors, distillation units, crystallizers, centrifuges, and vacuum dryers. The emission of volatile organic compounds from these sources shall be controlled by means of surface condensers or other equivalent controls.

(A) If surface condensers are used, the condenser outlet gas temperature must not exceed the following:

When VOC Vapor Pressure At 68°F (20°C) Exceeds	Outlet gas Maximum Temperature
5.8 psia (40 kPa)	-13°F (-25°C)
2.9 psia (20 kPa)	5°F (-15°C)
1.5 psia (10 kPa)	32°F (0°C)
1.0 psia (7 kPa)	50°F (10°C)
0.5 psia (3.5 kPa)	77°F (25°C)

(B) If equivalent controls are used, the volatile organic compound emissions must be reduced by at least as much as they would have been reduced by the use of a surface condenser which meets the requirements in paragraph (1)(A) of this section.

(2) Air dryers and exhaust systems. Volatile organic compound emissions from all air dryers and production equipment exhaust systems shall be reduced by at least 90 percent of the uncontrolled emissions or to 33 lb/day (15 kg/day) whichever is the least stringent limit.

(3) Loading Facilities. Emissions from truck or railcar deliveries to storage tanks with capacities greater than 2,000 gallons (7,500 liters) that store volatile organic compounds with vapor pressures greater than 4.1 psia (28 kPa) at 68°F (20°C) shall be reduced by at least 90% of the uncontrolled emissions by means of a vapor balance system or equivalent control.

(4) Tanks.

(A) All in-process tanks that contain volatile organic compounds at any time shall be kept covered, except when production, sampling, maintenance, or inspection procedures require operator access.

(B) All storage tanks that store volatile organic compounds which have vapor pressures greater than 1.5 psia (10.3 kPa) at 68°F (20°C) shall have pressure vacuum conservation vents installed which are set at ±0.8 inches of water (±0.2 kPa), unless a more effective control system is used.

(5) Centrifuges and Filters. Centrifuges, rotary vacuum filters and other filters having an exposed liquid surface which process liquids containing volatile organic compounds with vapor pressure equal to or greater than 0.5 psia (3.4 kPa) at 68°F (20°C) shall be enclosed.

(6) Liquid Leaks. All leaks from which any liquid containing volatile organic compound can be observed running or dripping shall be repaired the first time the equipment is off-line long enough to complete the repair.

§115.232. Exemptions.

(a) Any facility in Bexar, Brazoria, Dallas, El Paso, Galveston, Gregg, Jefferson, Nueces, Orange, Tarrant, or Victoria County which, when uncontrolled, will emit a combined weight of volatile organic compounds less than 550 pounds (250 kg) in any consecutive 24-hour period is exempt from the provisions of §115.231 of this title (relating to Control Requirements).

(b) Any facility located in Harris County which, when uncontrolled, will emit a combined weight of volatile organic compounds less than 15 pounds (6.8 kg) in any consecutive 24-hour period is exempted from the provisions of §115.231 of this title (relating to Control Requirements).

§115.233. Compliance Schedule and Counties.

The provisions of §115.231 of this title (relating to Control Requirements) shall apply within Bexar, Brazoria, Dallas, El Paso, Galveston, Gregg, Harris, Jefferson, Nueces, Orange, Tarrant, and Victoria Counties. All affected persons shall submit a final control plan to the Texas Air Control Board no later than December 31, 1980, and shall be in compliance with these rules as soon as practicable but no later than December 31, 1982.